

REMARKS

1. *Status of claims*

After entry of the above amendment, claims 82-102 and 125-128 are pending and under consideration.

2. *Support for amendment*

The amendments find support in the specification at p. 2, lines 1-11, and p. 7, lines 3-6, and in the Abstract. No new matter has been added by this amendment.

3. *Claim objections*

The Examiner objected to claim 83 for reciting the word "xenogeneic" instead of "xenogenic." By the above amendment, Applicants have made appropriate correction, and respectfully submit the basis for this objection has been removed.

4. *Claim rejections under 35 U.S.C. § 103(a)*

The Examiner rejected claims 82-88, 91-102, and 125 as being unpatentable over Gan, *et al.*, US 5,964,807 ("Gan") in view of Mechanic, US 5,854,397 ("Mechanic") and as evidenced by Matsuzaki, *et al.*, *Spine* 21(2):178-183 (1996). In light of the above amendment, Applicants respectfully traverse this rejection.

By the above amendment, claim 82 and all claims dependent thereon recite obtaining donor nucleus pulposus tissue comprising harvested extracellular matrix materials; and cross linking at least a portion of the nucleus pulposus tissue.

The Examiner alleges Mechanic teaches a process for crosslinking proteinaceous material and Gan teaches a hybrid material comprising intervertebral disc cells and a biodegradable support substrate, wherein the intervertebral disc cells are nucleus pulposus cells which may be obtained from the patient or from donor tissue. The Examiner also points to Matsuzaki as teaching that intact nucleus pulposus cells actively synthesize collagen. The Examiner further alleges the person of ordinary skill in the art would then find it obvious to use the hybrid material of Gan in the process of Mechanic, which would then allegedly produce the method recited by the present claims.

Mechanic fails generally to teach a method of manufacturing an intervertebral disc implant and, as noted by the Examiner, specifically “does not teach nucleus pulposus tissue.” Gan teaches the use of donor nucleus pulposus *cells*, but not tissue comprising an extracellular matrix component harvested from the donor. Although Gan notes “tissue may be extracted from the nucleus pulposus of lumbar discs, sacral discs and cervical discs,” that tissue, including extracellular matrix components thereof, subsequently is discarded to obtain isolated nucleus pulposus cells (col. 8, lines 50-61). These isolated cells are then combined with materials intended to substitute for the discarded nucleus pulposus tissue from which they were isolated and/or are cultured (*ibid.*). Thus, Gan teaches away from the use of “an extracellular matrix component harvested from the donor.”

Matsuzaki does nothing to redirect the skilled artisan toward such a use, but simply confirms the prophetic disclosure of Gan regarding the ability of isolated nucleus pulposus cells to synthesize collagen (col. 11, lines 15-22). Moreover, any collagen synthesized by the isolated nucleus pulposus cells of Gan would *not* be an extracellular matrix component harvested from a donor.

Therefore, Applicants submit claims 82-88, 91-102, and 125 are patentable over Gan in view of Mechanic as evidenced by Matsuzaki, and respectfully request this rejection be withdrawn.

Second, the Examiner rejected claims 89-90 as being unpatentable over Gan in view of Mechanic and further in view of Moore, *et al.*, US 6,350,732 ("Moore"). The Examiner alleges Moore teaches a method for extracting lipids from a collagenous tissue sample. Applicants respectfully traverse this rejection.

Gan and Mechanic have been discussed above with respect to independent claim 82 and claims dependent thereon. As a threshold matter, claims 89-90, which depend on claim 82, are patentable for at least the reasons noted above. In addition, Moore, like Mechanic, fails to teach nucleus pulposus tissue comprising an extracellular matrix component harvested from the donor and does nothing to remedy the deficiencies of Gan in this regard. As such, the teachings of Moore, combined with those of Gan and Mechanic, would not lead the person of ordinary skill in the art to the presently claimed invention.

Therefore, Applicants submit claims 89-90 are patentable over Gan in view of Mechanic and Moore and respectfully request this rejection be withdrawn.

5. *Conclusion*

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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